Atty Docket No.: 10123/03601

REMARKS

Claims 1 - 5, 7 - 19 and 21 - 24 remain pending in the present application. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1 - 5, 7 - 8, 11 - 13, 18 - 19, 21 and 23 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,125,893 to Dryden. ("Dryden"). (*See* 9/24/2007 Office Action, pp. 2 - 3).

Claim 1 recites *a connector for injecting fluid to a catheter*, comprising "an attachment portion adapted to fluidly couple to a source of pressurized fluid" and "*a bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve*" in combination with "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level."

In contrast, Dryden shows a connector 17 which allows a catheter 28 to pass therethrough to enter the lung and suction fluids directly therefrom. No fluids are *injected* to the catheter 28 whatsoever and no valve *of the catheter* is opened at any time in the device of Dryden. The only supply of pressurized fluids in the device of Dryden is via the machine 14 which supplies a breathing mixture to the lungs. The machine 14 is downstream of the valve 23 which is maintained closed by the pressure of the breathing mixture to allow this fluid to pass to the lungs.

> When it is desired to do suctioning, the adapter 17 may be held in one hand and the catheter tube [28] advanced to the left in the direction of the arrow 38 through the valve 23 and fitting 17 and endotracheal tube until its distal end is in the lung area where secretions are to be removed.

Specification, col. 2, lines 45 - 50.

Irrigation is also applied directly into the lungs in the area where secretions to be withdrawn are thick. (Specification, col. 3, lines 17 - 21). That is, for suction and irrigation the catheter 28 is passed through the valve 23 and the entire adapter 17 until the distal end 32 extends into the

lungs. Fluids supplied to the catheter 28 via the fluid source 12 pass through the entire catheter 28 and exit the distal end thereof directly into the lung. Whether or not there is a valve at 36, this valve is never bypassed and no fluids are ever injected into the endotracheal tube from the fluid source 12. Fluids are then suctioned into the catheter 28 and pass therethrough to the suction machine 13. Thus, the adapter 17 is not *for injecting fluid to a catheter* as recited in claim 1 and the valve 23 is not "*a valve of the catheter*" nor is the valve 23 opened "*to permit fluid to flow into the catheter without impinging on the valve*," as recited in claim 1.

Furthermore, Dryden fails to teach or suggest "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level", as recited in claim 1. The Examiner asserts that the valves 35 and 36 of the Dryden device are fully capable of being adapted to maintain a pressure of fluid within the connector below a threshold value. (*See* 9/24/07 Office Action, p. 3). However, it is noted that the valves 35 and 36 control only the pressure within the catheter 28 and have no impact on the pressure within the adapter 17. The pressure within the adapter 17 is controlled only by the pressure supplied from the source 14. (Specification, col. 2, lines 50 - 56). In any case, there is no disclosure of any pressure control function of either of the valves 35 and 36 which appear to perform no more than simple on/off functionality. Accordingly, it is respectfully submitted that the Dryden fails to teach or suggest "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level," as recited in claim 1.

The Examiner has further relied on a 35 U.S.C. § 103(a) rejection to overcome this deficiency in the Dryden device. Specifically, the Examiner asserts that it would have been obvious to have constructed the valve 35 as a pressure control element, as such valves are known in the art, further citing U.S. Patent No. 4,124,525 to Binard et al. to establish this argument. (*See* 9/24/07 Office Action, p. 3).

It is submitted that the cited references provide no motivation to modify the Dryden device to include "an overpressure control element," as recited in claim 1. As the Dryden device is simply for low pressure applications including the supply of a breathing mixture and suctioning of mucus, it is submitted that those skilled in the art would have seen no need for such an overpressure control element. Thus, it is respectfully submitted that obviousness can not be established by combining or modifying the teachings of the prior art to produce the claimed

invention where there is no teaching, suggestion, or motivation to do so and that this represents an impermissible hindsight reconstruction of the invention. (*See* In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)).

It is therefore respectfully submitted that Dryden fails to show or suggest *a connector for injecting fluid to a catheter*, comprising "an attachment portion adapted to fluidly couple to a source of pressurized fluid" and "*a bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve*" in combination with "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level," as recited in claim 1 and that claim 1 is allowable over Dryden. Because claims 2 - 5, 7 - 8 and 11 - 13 depend from and, therefore, include the limitations of claim 1, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

Independent claim 18 includes limitations substantially similar to those of claim 1 discussed above. Specifically, claim 18 recites "an elongated tube extending between *a first end adapted for fluid connection to a power injector* and a second end adapted for fluid connection to *a catheter including a valve in a proximal part thereof*, the second end being *insertable into the catheter beyond the valve thereof* so that fluid passes through the fluid coupler into the catheter to a distal end thereof *without passing through the valve* and a pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level." Applicants respectfully submit that claim 18 is allowable over Dryden for the same reasons noted above in regard to claim 1. Because claims 19, 21 and 23 depend from and, therefore, include the limitations of claim 18, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

Claims 9 - 10, 22 and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Dryden in view of U.S. Pat. No. 6,375,637 to Campbell et al. ("Campbell"). In support of the rejection, the Examiner states that Dryden teaches the device as claimed except for the overpressure control element being an extension tube and having an external collection jacket disposed therearound. The Examiner references the Campbell device to overcome this deficiency. (*See* 9/24/07 Office Action, p. 5).

As stated above in regard to claim 1 from which these claims depend, Dryden fails to teach or suggest the limitations of claim 1. It is submitted that Campbell fails to cure these deficiencies. The Campbell device is directed to a catheter balloon having a controlled failure mechanism therein. (*See* Campbell, col. 4, ll. 55-58). The Campbell device fails to overcome the deficiencies of the Dryden device, particularly "a bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a valve of the catheter to permit fluid to flow into the catheter without impinging on the valve", as recited in claim 1. It is therefore submitted that Dryden and Campbell, either alone or in combination, fail to teach or suggest the limitations of claim 1. Because claims 9 and 10 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 18 recites limitations substantially similar to claim 1, including "*an elongated tube extending between a first end adapted for fluid connection to a power injector* and a second end adapted for fluid connection to a catheter including a valve in a proximal part thereof, *the second end being insertable into the catheter beyond the valve thereof so that fluid passes through the fluid coupler into the catheter to a distal end thereof without passing through the valve* and a pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level." It is respectfully submitted that Dryden and Campbell, either alone or in combination, fail to teach or suggest the limitations of claim 18. Because claims 22 and 24 depend from and therefore include all of the limitations of claim 18, it is respectfully submitted that these claims are also allowable.

Claims 14 - 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Dryden. In support of the rejection, the Examiner states that Dryden teaches the device as claimed except for the threshold level of approximately 300, 100, 80 or 40 psi. The Examiner states that this modification would have been obvious to one skilled in the art. (*See* 9/24/07 Office Action, pp. 5-6).

Claims 14 - 17 depend from, and therefore include all of the limitations of claim 1. As noted above, Dryden fails to teach or suggest the limitations of claim 1. Thus it is respectfully submitted that claims 14 - 17 are allowable for at least the same reasons stated above in regard to claim 1. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claim 14 - 17.

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In light of the foregoing, Applicants respectfully submit that all of the now pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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